



CONGRESSIONAL BUDGET OFFICE COST ESTIMATE

October 9, 2002

H.R. 5478 **Patient Safety and Quality Improvement Act**

*As ordered reported by the House Committee on Energy and Commerce
on September 25, 2002*

SUMMARY

H.R. 5478 would expand the duties of the Agency for Healthcare Research and Quality (AHRQ). AHRQ would be required to establish credentialing procedures for patient safety organizations (PSOs), which collect patient safety data voluntarily submitted by health care providers for inclusion in a patient safety database. The bill also would establish privacy protections and impose civil monetary penalties for violations of those protections. AHRQ would be required to report to the Congress on effective strategies for reducing medical errors and increasing patient safety.

The bill would require the Secretary of Health and Human Services to develop methodologies for the collection of patient safety data and provide technical assistance to PSOs and states. In addition, the Secretary would, with the National Committee for Vital and Health Statistics, develop voluntary national standards that promote the comparability of medical information technology systems.

H.R. 5478 would authorize grants to qualified practitioners for the purpose of establishing electronic prescription programs, and would authorize the Health Resources and Services Administration (HRSA) to make grants to hospitals and other health care providers for acquiring or implementing information technologies. The bill would require the inclusion of a unique product identifier on packaging of a drug or biological product that is subject to regulation by the Food and Drug Administration (FDA). Drugs and biological products that do not comply with FDA's labeling requirements would be deemed misbranded, and their manufacturers and packagers would be subject to civil penalties.

CBO estimates that implementing H.R. 5478 would cost \$17 million in 2003 and \$650 million over the 2003-2007 period, assuming the appropriation of the necessary amounts. CBO estimates that receipts from fines for violation of the privacy protections would amount to less than \$500,000 a year.

H.R. 5478 would preempt state laws that would govern the disclosure of information provided to patient safety organizations, and it would prevent health care providers from taking certain actions against employees because the employee provided information to patient safety organizations. While these provisions would be intergovernmental mandates as defined in the Unfunded Mandates Reform Act (UMRA), they would impose no requirements on states that would result in additional spending; thus, the threshold as established by UMRA (\$58 million in 2002, adjusted annually for inflation) would not be exceeded.

The bill would impose private-sector mandates, as defined in UMRA, on health care providers and on manufacturers, packagers, and labelers of drugs and biological products. Because the specific requirements of the bill would depend on future actions by the Secretary of Health and Human Services, however, CBO cannot determine whether the direct cost of the mandates would exceed the annual threshold specified in UMRA (\$115 million in 2002, adjusted annually for inflation).

ESTIMATED COST TO THE FEDERAL GOVERNMENT

The estimated cost of H.R. 5478 is shown in the following table. The bill could also result in an increase in revenues from fines, but CBO estimates that any such increase would be less than \$500,000 a year. The costs of this legislation fall within budget function 550 (health).

	By Fiscal Year, in Millions of Dollars				
	2003	2004	2005	2006	2007
CHANGES IN SPENDING SUBJECT TO APPROPRIATION					
Estimated Authorization Level	51	226	149	128	134
Estimated Outlays	17	235	144	124	129

BASIS OF ESTIMATE

Spending Subject to Appropriations

H.R. 5478 would expand the current duties of AHRQ. The new duties would include providing technical assistance to states that have (or are developing) systems for reporting medical errors. AHRQ also would oversee the certification and recertification of PSOs, which collect patient safety data from health care providers. (PSOs are private or public organizations that conduct activities to improve patient safety and the quality of health care delivery.) PSOs would not receive funding under this bill. In addition, the bill would require AHRQ to establish a patient safety database to collect, support, and coordinate the analysis of patient safety data that is reported on a voluntary basis. AHRQ would also develop an Internet-based mathematical model that simulates the cost and effectiveness of electronic prescription programs. Based on information from AHRQ, CBO expects that these tasks would require increased staff for providing assistance to states, oversight of PSOs, and collection and maintenance of the patient safety database. They would also require additional computer resources for the database. CBO estimates that the agency would need additional appropriations of \$12 million in 2003 and \$64 million over the 2003-2007 period to carry out these responsibilities. We estimate that outlays would total \$4 million in fiscal year 2003 and \$52 million over the 2003-2007 period, assuming the necessary amounts are appropriated.

The bill would require the Secretary to provide scientific support to PSOs and to develop methodologies for collecting data on patient safety. In addition, the Secretary would be required to develop voluntary, national standards that promote the compatibility of health care information technology systems across all health care settings. CBO estimates that these efforts would cost less than \$500,000 a year.

H.R. 5478 would allow the Secretary to make grants to qualified practitioners for the purpose of establishing electronic prescription programs. AHRQ would conduct a study and report to the Congress on the effectiveness and cost-effectiveness of electronic prescription programs.

CBO assumes that grants would begin to be awarded in 2004, and that initially about 10 percent of the estimated one million practitioners licensed to write prescriptions would receive grants. The estimate assumes that grants would be awarded to 20 percent of eligible practitioners by 2007. CBO estimates that providers face an average start-up cost of about \$3,500 for participation in an electronic prescription program. The bill stipulates that grants cover no more than 50 percent of the costs to establish an electronic prescribing program. Thus, on average, providers would expect to receive a grant of about \$1,750. Pharmacies would also be eligible to receive grants for their role in receiving and processing

electronically submitted prescriptions. While most pharmacies currently have the capability to receive and transmit data on prescription drugs, the industry would need to upgrade current technology to address compatibility issues. CBO estimates that this grant program would require additional appropriations of \$5 million in fiscal year 2003 and \$450 million over the 2003-2007 period.

HRSA would make grants available to hospitals and other health care providers for acquisition or implementation of information technology systems. Based on similar HRSA programs, CBO estimates that these grants would cost an additional \$8 million in 2003 and \$148 million over the 2003-2007 period, assuming appropriation of the necessary amounts.

The bill would require the inclusion of a unique product identifier on packaging of a drug or biological product that is subject to regulation by the Food and Drug Administration. This provision would cost the FDA less than \$500,000 per year to implement.

Revenues

Because those prosecuted and convicted for violation of the bill's privacy provisions could be subject to civil monetary penalties, the federal government might collect additional fines if the bill is enacted. Drugs and biological products that do not comply with FDA's labeling requirements would be deemed misbranded, and their manufacturers and packagers would be subject to civil penalties. Collections of civil fines are recorded in the budget as governmental receipts (revenues). CBO estimates that any additional receipts would be less than \$500,000 a year.

ESTIMATED IMPACT ON STATE, LOCAL, AND TRIBAL GOVERNMENTS

H.R. 5478 would preempt any state freedom of information law or other laws governing civil or administrative procedure that would require the disclosure of information provided by a health care provider to a certified patient safety organization. This preemption would be an intergovernmental mandate as defined in UMRA because it would limit the application of those state laws. Another intergovernmental mandate in the bill would prohibit health care providers (including public entities) from using the fact that an employee reported patient safety data in an adverse employment action against the employee. CBO estimates that these mandates would impose no requirements on states that would result in additional spending; thus, the threshold as established by UMRA (\$58 million in 2002, adjusted annually for inflation) would not be exceeded.

ESTIMATED IMPACT ON THE PRIVATE SECTOR

The bill contains private-sector mandates, as defined in UMRA, on manufacturers, packagers, and labelers of drugs and biological products and on health care providers. Because the specific requirements of the bill would depend on the future actions of the Secretary of Health and Human Services, however, CBO cannot determine whether the direct cost of the mandates would exceed the annual threshold specified in UMRA (\$115 million in 2002, adjusted annually for inflation).

Under the bill, manufacturers, packagers, and labelers would be required to include a computer-scannable unique product identifier on the packaging of drugs and biological products. Many drug products are currently labeled with such identifiers, but many are not. Of the approximately 200,000 over-the-counter and prescription drug products currently on the market, over one quarter are over-the-counter drugs—nearly all of which already contain universal product codes. A small percentage of prescription drugs administered in hospitals currently are labeled with computer-scannable unique product identifiers. It is unclear whether existing identifiers would meet the requirements of the Secretary.

Adding unique product identifiers would impose costs for products that do not now contain them, and potentially for products that already contain similar information. Under the bill, the Secretary would determine how much standardization of identifiers would be required. The Secretary also would determine what information would have to be included on the identifiers. If identifiers were required to include only the National Drug Code associated with that product, for example, industry costs would be lower than if the identifiers also had to include the lot number and expiration date of the product. The specific details of the requirements imposed by the Secretary, including how quickly the new requirements would have to be implemented, would determine whether the cost of this mandate would exceed the threshold specified in UMRA.

The bill also would impose a mandate on health care providers, by not allowing them to use the fact that an employee reported patient safety data in an adverse employment action against the employee. This mandate would not have any direct cost, however, because there are no activities that health care providers would undertake under current law that they would be prohibited from undertaking under the bill (because patient safety data, as defined in the bill, do not exist under current law).

PREVIOUS CBO ESTIMATE

On September 26, 2002, CBO transmitted a cost estimate for H.R. 4889, the Patient Safety Improvement Act of 2002, as ordered reported by the House Committee on Ways and Means

on September 18, 2002. CBO estimated that implementing the provisions of that bill would increase discretionary spending by \$58 million over five years. The difference in the estimate of discretionary outlays between H.R. 4889 and H.R. 5478 is largely due to the addition of the grant program for establishing an electronic prescription program under H.R. 5478. In addition, H.R. 4889 contained a provision imposing criminal fines for violations of patient privacy. Criminal fines are deposited as receipts in the Crime Victims Fund and later spent; thus, they create direct spending authority. Individuals prosecuted and convicted for violation of privacy provisions in H.R. 5478 could be subject to civil monetary penalties only, not criminal fines. Therefore, this bill would not result in direct spending.

H.R. 5478 would require the inclusion of a unique product identifier on packaging of a drug or biological product that is subject to regulation by the FDA. This provision, which creates a private-sector mandate, is not included in H.R. 4889. H.R. 5478 would amend the Public Health Service Act, and would impose a mandate on health care providers by not allowing them to use the fact that an employee reported patient safety data in an adverse employment action against the employee. Because H.R. 4889 would amend the Social Security Act, its requirement would only apply to providers who choose to participate in the Medicare program; thus, it would not impose a private-sector mandate on providers.

ESTIMATE PREPARED BY:

Federal Revenues and Outlays: Alexis Ahlstrom, Julia Christensen, Margaret Nowak, and
Chris Topoleski
Impact on State, Local, and Tribal Governments: Leo Lex
Impact on the Private Sector: Daniel Wilmoth

ESTIMATE APPROVED BY:

Robert A. Sunshine
Assistant Director for Budget Analysis